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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,487	01/07/2002	Spiros Fotinos	366325-509	3570

25561 7590 09/23/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/23/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,487

Applicant(s)

FOTINOS ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Examiner acknowledges receipt of declaration filed 03/01/02 and IDS filed 10/07/02.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5 and 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is selecting cosmetic agent from the group consisting of anti-acne agents. The "group consisting of" requires that the cosmetic agent be selected from two or more groups of agents. Claim 23 is vague and indefinite because it is not clear what is rinsed from the skin and the claim is confusing.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6-8, 20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lorenz et al. (US 5,420,197).

Lorenz discloses a composition that comprises polyvinylpyrrolidone (abstract, column 2, line 34, column 3, line 43 and column 4), wetting, dispersing agents or surfactants (column 5, line 11), glycerin and polyethylene glycol (column 5, lines 17-24), biologically active

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agents or cosmetic agents (column 5, lines 38-57) and the composition may also have fragrances, dyes, pigments and fillers (column 5, lines 25-31). Among biologically active agents useful in the composition of Lorenz are sympathomimetic agents, cardiovascular agents, antibacterial agents, antifungals, antivirals, antimicrobials and anesthetics (column 5, lines 39-51). Hydrating agents are added to the composition when the composition is a cosmetic composition (column 5, lines 54-56). The composition is formulated as drug delivery patches, skin masks or wraps and dry film products (column 6, lines 6-26). A patch is a disc/disk and a patch anticipates a disc/disk. Lorenz discloses dermal or topical application of the composition described above to skin (column 5, line 57) by wetting the skin and applying the composition to the skin (column 6, line 22). Lorenz applies the composition to wet skin in the manner of claim 22 and thus meets the method would inherently clean the skin. The teaching of Lorenz meets the limitations of the claims.

5. Claims 1, 3 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonard et al. (US 4,820,525).

Leonard discloses a transdermal/transmucosal delivery system that comprises a polyethylene polymer and estradiol in the form of disk (column 1, lines 36-43 and examples 1 and 3). Instant claim 21 recites application of delivery disk comprising polymer and active substance to the mucosa of a subject. Transmucosal delivery system in a disk form implies application of a composition comprising estradiol and polyethylene polymer to the mucosa. Thus the teaching of Leonard meets the limitations of the claims.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al. (US 5,420,197).

Lorenz discloses the delivery system of the instant claims. Lorenz does not disclose that amounts of additives in the composition as recited in the instant dependent claims. There is no demonstration in the instant application that the use of polyethylene glycol 4000 in the instant composition provides unusual results. The amounts recited in the instant claims may represent optimization of the composition and “[where] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation.” Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Lorenz. One having ordinary skill in the art would have been motivated to prepare a composition where the amounts of the additives are optimized to yield a delivery composition that would be expected to deliver active substances at the site of delivery at a desired rate of delivery.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

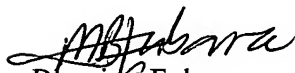
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Blessing Fubara
Patent Examiner
Tech. Center 1600